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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

WHITEMAN, BRIAN A

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 02/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/824,757 | KANEDA, YASUFUMI | |
| | Examiner | Art Unit | |
| | Brian Whiteman | 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-14, 16, 18 and 20-32 is/are pending in the application.
- 4a) Of the above claim(s) 4, 25, 28 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-9, 11-14, 16, 18, 20-24, 26, 27, 29-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/937,839.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/14/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Non-Final Rejection

Claims 1-9, 11-14, 16, 18, 20-32 are pending.

The amendment to claims 1-8, 11-14, 16, and 18, the cancellation of claims 10, 15, 17, and 19, and the addition of claims 21-32 in paper filed on 4/14/04 is acknowledged by the examiner.

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: a virus belonging to a family selected from the group consisting of: Retroviridae, Togaviridae, Coronaviridae, Flaviviridae, Paramyxoviridae, Orthomyxoviridae, Bunyaviridae, Rhabdoviridae, Poxviridae, Herpesviridae, Baculoviridae, and Hepadnaviridae in claims 3, 24, 27, and 31.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 13, 14, and 18 are generic.

During a telephone conversation with Jacqueline Mahoney on 1/24/06 a provisional election was made without traverse to prosecute the species Herpesviridae in claims 3, 24, 27, and 31. Affirmation of this election must be made by applicant in replying to this Office action. The species in claims 4, 25, 28, and 32 and species Retroviridae, Togaviridae, Coronaviridae, Flaviviridae, Paramyxoviridae, Orthomyxoviridae, Bunyaviridae, Rhabdoviridae, Poxviridae,

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Baculoviridae, and Hepadnaviridae in claims 3, 24, 27, and 31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species.

Priority

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No.09/937,839, filed on 2/21/02.

The status of the parent application needs updated in the cross-reference on page 1 of the instant specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 9 recite the limitation "the detergent". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6-9 and 20-22 are directed to a product by process. Thus, if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

The intended use in claims 11-14 and 24-27 does not have patentable weight over the prior art that teaches a product with the same structure. See MPEP 2111-2111.02.

Claims 1, 2, 5, 6, 7, 11, 12, 13, 14, 15, 18, 20, 23, 26, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Hoon et al. (US 6,472,375).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Hoon teaches a viral liposome vector comprising fused HVJ, which contains a viral envelope, with nonviral reagents for delivery of nucleic acid encoding a tumor-associated antigen into a tumor or an organ (column 3, lines 5-9, column 13, line 29, and Fig. 1). Hoon

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further teaches mixing the HVJ with a plasmid (columns 4 and 8). Hoon further teaches preparing HVJ comprising purifying the virus, inactivating the virus, and precipitated by centrifugation (column 8).

Claims 1, 2, 5, 6, 7, 11, 12, 13, 14, 15, 18, 20, 23, 26, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Hoon et al. (US 6,432,925).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Hoon teaches a viral liposome vector comprising fused HVJ, which contains a viral envelope, with nonviral reagents for delivery of nucleic acid encoding a tumor-associated antigen into a tumor or an organ (column 3, lines 5-9, column 13, line 29, and Fig. 1). Hoon further teaches mixing the HVJ with a plasmid (columns 4 and 8). Hoon further teaches preparing HVJ comprising purifying the virus, inactivating the virus, and precipitated by centrifugation (column 8).

Claims 1, 2, 5, 6, 7, 8, 11, 12, 13, 14, 15, 16, 18, 20, 21, 23, 26, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Ramani et al. (PNAS, 95:11886-11890, 1998). Ramani teaches a F-virosomes (Sendai virus) containing pCIS3CAT or pBVluc DNA (page

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11886). The plasmid was incubated with detergent (Triton-X100) solubilized fraction of Sendai virus containing its envelope using a previous known method in the prior art (page 11886). The F-virosomes were heat treated (page 11886).

Claims 1-3, 5, 11-14, 16, 18, 23, 24, 26, 27, 30, and 31 are rejected under 35

U.S.C. 102(b) as being anticipated by Roizman (US 5,846,707). Roizman teaches a herpes simplex virus comprising a foreign gene operably linked to a promoter and method of making the virus. See columns 1, 2, and 9-10.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1, 2, 5-7, 11-14, 16, 18, 20, 23, 26, 29 and 30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6,913,923. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are directed to a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope and method of producing the gene transfer vector.

Claims 1, 2, 5-9, 11-14, 16, 18, 20-23, 26, 29 and 30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-49 of copending Application No. 11/126,770. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are directed to a gene transfer vector comprising an exogenous gene encapsulated in a native virus envelope and producing a gene transfer vector.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 5, 6, 7, 11, 12, 13, 14, 16, 20, 23, and 26 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-23 of copending Application No. 10/485,752. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are directed to a gene transfer vector.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635

